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09/928,464

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

05/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|-------------------------------------|--|
| Office Action Summary | Application No. 09/928,464 | Applicant(s) BOYLE ET AL. | |
| | Examiner VICTORIA P. CAMPBELL | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,9-28,30 and 34-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,29 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the second Office Action following the second Request for Continued Examination based on the 09/928464 application filed August 13, 2001. Claims 1-5, 7, 8, 29, and 31-33 as amended July 23, 2007 are currently pending and considered below.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by USPN 4,747,833 to Kousai et al.

Regarding the above claims, Kousai et al disclose a delivery sheath for a medical device comprising a flexible, elongate tube (12; Col. 3, lines 17-23) having a proximal end and a distal end (Fig. 4) being sized and adapted to fit within a biological blood vessel (4); and a resealable longitudinal joint (10) having a first side (Fig. 7, #13) and a second side (Fig. 7, #12), the second side having an opening (See Fig. 7) and the first side having an outwardly extending protrusion (13a) adapted to fit within the opening. Kousai et al further teach that the protrusion has a neck leading to a head, the head being larger than the neck (See Fig. 7); and the opening leads to a cavity, the opening smaller than the head and the cavity within a range of slightly smaller to larger than the

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head (Fig. 7). Kousai et al also disclose that there is a single lumen formed within the elongate tube (Fig. 5), that the longitudinal joint extends throughout the entire length (Fig. 4), or that the longitudinal joint extends from the proximal end to a position proximal the distal end (Fig. 9; the linear portion 13 would terminate slightly before the film 12a during the distal taper shown in Fig. 4), that the longitudinal joint extends from the tube surface to the tube lumen (Fig. 7), and that the lumen is capable of being pressurized up to and over 8 atm (Abstract, the examiner considers 8 atm to be under the threshold of "reasonable force" needed to pull the device apart).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 29 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kousai et al in view of USPN 6,080,141 to Castro et al.

Regarding the above claims, Kousai et al teach a delivery system comprising a sheath (11) including a flexible elongate tube (12; Col. 3, lines 17-23) having at least one lumen (Fig. 5) extending the length of the tube and a self-resealable longitudinal joint (10) having a first side (Fig. 7, #13) and a second side (Fig. 7, #12), the second side having an opening (See Fig. 7) and the first side having an outwardly extending protrusion (13a) adapted to fit within the opening, the tube being sized to fit within a biological blood vessel (4); a guide wire distributed through the length of the lumen (15, Fig. 11), and a device configured to split the longitudinal joint and allow the sheath to be removed from the guide wire (Fig. 10). Kousai et al further teach that the splitting device further comprises a ring having a lumen (21, 22), the ring fitting over the sheath (Fig. 10); and a blade (23) aligned with a longitudinal axis of the ring and being coupled to the surface of the lumen of the ring (Fig. 10), a height of the blade being sufficient to extend into the lumen of the sheath and including a distal edge for cutting the sheath during relative longitudinal movement between the ring and the sheath (as material is

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fed through the mandrel, nozzle 23, acting as a blade, cuts the molten material and separates it around insert 13). Kousai et al further teach that the ring further comprises a guide mandrel (unlabeled, Fig. 10, central mandrel) coupled to the edge of the blade, configured to be positioned in the lumen of the sheath. Kousai et al do not teach or disclose a handle or a device coupling the handle to the proximal portion of the device.

Castro et al teach a splittable catheter similar to the one described by Kousai et al having a handle (16) disposed at a proximal portion of the sheath (11) and a device coupling the proximal portion of the sheath to a distal portion of the handle (15), wherein the device for coupling is split along the length of the device (Fig. 2).

At the time of invention it would have been obvious to one having ordinary skill in the art to add the split coupling member and handles of Castro et al to the splittable catheter of Kousai et al in order to provide a larger gripping area to facilitate splitting of the catheter (Col. 4, line 67; Col. 5, lines 35-37).

Response to Arguments

7. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763